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DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Refer to: FEI 3003237261

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

01-BLT-17

February 28, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Charles J. Wampler, II, President
Hawk Valley Dairy, Inc.
11173 Hawk Valley Lane
Fulks Run, Virginia 22830

RE: Case No. 00-0931-VA

Dear Mr. Wampler:

An inspection of your dairy located at 11173 Hawk Valley Lane, Fulks Run, Virginia by our investigators on February 7 to 8, 2001, confirmed that you offered an animal for sale for slaughter as human food in violation of Section 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On or about July 13, 2000, you sold a culled dairy cow bearing back tag # [redacted] and farm tag # [redacted]. This cow was subsequently delivered to and sold for slaughter as human food at [redacted] on or about July 14, 2000. United States Department of Agriculture's (USDA) analysis of tissue samples collected from this animal identified the presence of gentamicin in the kidney at 9.28 parts per million (ppm). Gentamicin is not approved for oral or injectable use in cattle. Therefore, there is no allowable tolerance for gentamicin in edible tissue of cattle. The presence of this drug in edible tissues of this animal causes the food from the animal to be adulterated. You should have received a letter dated August 1, 2000, from USDA concerning this matter.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to

health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply.

For example, our investigators noted the following conditions on your farm:

1. You lack adequate documentation that animals have been treated including the drug dosage administered to each animal and the drug withdrawal time(s);

2. You lack a system for assuring that drugs are used in a manner that conforms to the approved labeling;

3. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal species, and;

4. You lack a system for assuring medicated animals have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.

Our inspection also revealed that the gentamicin residue came from your use of Gentocin on your dairy herd. You informed our investigators that the veterinarian had prescribed the gentamicin for the treatment of scours and pneumonia in calves. Although you had a prescription for gentamicin, it was not for the treatment of dairy cows and can be considered "extra-label use," which is a deviation from Title 21, Code of Federal Regulations (21 CFR), Part 530. Our inspection also disclosed that the withdrawal time stated on the prescription label of gentamicin was four days for milk and six months for meat. From our experience with other gentamicin cases, the withdrawal period for gentamicin in meat is up to 18 months, not six months. Use of gentamicin to treat mastitis in dairy cows constitutes "extra-label use" of a new animal drug in a food-producing animal in a manner that is not in accordance with the drug labeling. Therefore, you adulterated gentamicin within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its approved labeling.

In October of 1994, Congress passed the Animal Medicinal Drug Use Clarification Act, which permits extra-label use under certain controlled conditions, specified in 21 CFR Part 530. Extra label use is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and in conformance with criteria set forth in 21 CFR Part 530.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

As a producer of animals offered for use as food, it is your responsibility to assure your operations are in compliance with the requirements of the Federal Food, Drug and Cosmetic Act. You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating the corrections have been made.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,

Lee Bowers
Director, Baltimore District

cc: Dr. Perfecto Sanitiago, District Manager
USDA/FSIS
5601 Sunnyside Avenue
Suite 1-2288 B
Beltsville, Maryland 20705-5200

cc: Virginia Department of Agriculture and Consumer Services
Division of Consumer Protection
Office of Meat & Poultry Services
P.O. Box 1163
Richmond, Virginia 23218